Hypertension Improvement Project
Randomized Trial of Quality Improvement for Physicians and Lifestyle Modification for Patients
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Abstract—Despite widely publicized hypertension treatment guidelines for physicians and lifestyle recommendations for patients, blood pressure control rates remain low. In community-based primary care clinics, we performed a nested, 2×2 randomized, controlled trial of physician intervention versus control and/or patient intervention versus control. Physician intervention included internet-based training, self-monitoring, and quarterly feedback reports. Patient intervention included 20 weekly group sessions followed by 12 monthly telephone counseling contacts and focused on weight loss, Dietary Approaches to Stop Hypertension dietary pattern, exercise, and reduced sodium intake. The primary outcome was change in systolic blood pressure at 6 months. Eight primary care practices (32 physicians) were randomized to physician intervention or control groups. Within those practices, 574 patients were randomized to patient intervention or control groups. Patient mean age was 60 years, 61% were women, and 37% were black. Blood pressure data were available for 91% of patients at 6 months. The main effect of physician intervention on systolic blood pressure at 6 months, adjusted for baseline pressure, was 0.3 mm Hg (95% CI: −1.5 to 2.2; P=0.72). The main effect of the patient intervention was −2.6 mm Hg (95% CI: −4.4 to −0.7; P=0.01). The interaction of the 2 interventions was significant (P=0.03); the largest impact was observed with the combination of physician and patient intervention (−9.7±12.7 mm Hg). Differences between treatment groups did not persist at 18 months. Combined physician and patient interventions lowers blood pressure; future research should focus on enhancing effectiveness and sustainability of these interventions. (Hypertension. 2009;54:1226-1233.)

Key Words: hypertension ■ blood pressure ■ behavioral intervention ■ quality improvement ■ lifestyle ■ DASH dietary pattern

Hypertension is the most prevalent risk factor for cardiovascular and kidney diseases1 and accounts for ≈35% of atherosclerotic cardiovascular disease.2 Antihypertensive therapy reduces the risk of stroke by ≈35%, congestive heart failure by 42%, and coronary heart disease by 28%.3 Prevention and treatment guidelines for providers and patients are readily available.4 Nonetheless, adherence to both provider guidelines and lifestyle recommendations for patients is low, resulting in continued low rates of blood pressure (BP) control.5 We tested interventions to increase physician adherence to national guidelines and patient adherence to lifestyle recommendations for lowering BP.

Methods
The Hypertension Improvement Project (HIP) was approved by the Duke Institutional Review Board. The design6 was a nested 2×2 randomized, controlled trial of a physician intervention, a patient intervention, and both combined, compared with neither. Nesting occurred both at the level of the practice and the level of the physician. Primary care practices were randomly assigned to the physician intervention (MD-I) or to the physician control (MD-C) group. All of the participating physicians within a given practice had the same randomization assignment. Within the participating practices, patients were individually randomized to the patient intervention (Pt-I) or to usual care (Pt-C). Follow-up measurements were performed at 6 and 18 months postrandomization. The primary outcome was systolic BP change at 6 months. The study design is displayed in Figure 1.

Enrollment and Randomization
Four matched pairs of community-based primary care practices in central North Carolina were randomized between 2005 and 2007. Practices were matched with regard to specialty (internal medicine or family practice) and patient socioeconomic mix. One practice of
each pair was blindly assigned by the study statistician to intervention or control status. Within each practice, all of the physicians were invited to participate, with a goal of enrolling 4 physicians per clinic. Each physician provided written informed consent. For logistical reasons, we enrolled practices in waves or “cohorts” of 1 intervention and 1 control clinic each.

We sent a recruitment letter from the physician to potentially eligible patients. We sought to enroll 10 to 15 patients from each physician. Patients were eligible if they were ≥25 years old and were hypertensive on the basis of billing codes. Patients were excluded if they had self-reported chronic kidney disease (CKD), a cardiovascular disease event within the past 6 months, or were pregnant, breastfeeding, or planning a pregnancy.

Potential study participants were prescreened by telephone and then attended 2 screening visits at which eligibility was confirmed, written informed consent was obtained, and baseline data were collected. Randomization to Pt-C or Pt-I occurred in varying block sizes using a computer-generated algorithm, stratified by cohort and clinic. Randomization was performed by the study statistician; all of the data collection staff remained blinded to the participant’s treatment assignment. It was not feasible to blind patients or providers to their own randomization assignment. Patients were asked not to discuss their randomization assignment with their provider, but strict blinding of the physicians was not feasible.

### Interventions

MD-I lasted 18 months and consisted of 3 elements. First, 2 training modules were provided on-line. The first module addressed the Seventh Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-7) guidelines, and the second addressed lifestyle modification for BP control. Each module required ~45 minutes, included a quiz that gave immediate feedback, and provided Continuing Medical Education credit through Duke University. Participating physicians completed the modules within 2 weeks of randomization and before the patient intervention began. Second, each physician in MD-I received an evaluation and treatment algorithm that summarized, on a color-coded, pocket-sized laminated card, the major JNC-7 guidelines, including lifestyle guidelines and a decision tree. Third, a quality improvement (QI) procedure assessed clinical performance measures and provided quarterly feedback to physicians on adherence to JNC-7 guidelines. At each MD-I site, participating physicians completed a clinical performance measure data form every time a HIP patient (in either Pt-I or Pt-C) had a clinic visit. The form recorded patient demographics, comorbidity, previous and current BP measurements, and actions taken during the visit. In addition, 1 day each month, physicians completed a clinical performance measure form on all of the adult patients treated during that day, whether or not the patient was a HIP participant, recording the same data as for study participants but without patient identifiers.

These data were converted into personalized quarterly feedback reports that indicated the following: (1) the proportion of hypertensive patients in the practice with adequately controlled BP, the change in that proportion over the course of the study, and comparison with the other participating physicians; (2) the proportion of patients with diabetes mellitus or CKD who were at JNC-7 goal BP; (3) the proportion of patients prescribed specific classes of medication on the basis of JNC-7 guidelines; and (4) the proportion who received lifestyle modification counseling on the basis of physician self-report.

MD-C constituted “usual care.” There was no attempt to change or monitor procedures already in place for QI and physician education with regard to BP control. No performance data were collected from these physicians, and no performance feedback was given.
Pt-I consisted of 20 weekly group sessions (n=10 to 15 patients per group) over ~6 months. All of the intervention sessions occurred at or near the patients’ primary care clinic.

The behavior goals of Pt-I included weight loss if overweight, the Dietary Approaches to Stop Hypertension (DASH) dietary pattern, increased moderate-to-vigorous physical activity, reduced sodium intake, and moderation of alcohol intake. In addition, the intervention promoted adherence to antihypertensive medication regimen. Pt-I was based on key theoretical constructs developed to guide health behavior change efforts and on practical applications from previous trials. The intervention was designed to promote frequent self-monitoring, feedback, goal setting, and social support and used motivational interviewing techniques.

Pt-I was conducted by 2 experienced behavioral interventionists who were trained and certified to deliver a group intervention focusing on diet and exercise and to use motivational interviewing techniques. They were assisted by community health advisors. Two community health advisors assisted with group sessions at each clinic and contacted participants who missed a session. After the initial 6-month intensive intervention, community health advisors contacted participants by telephone each month for 1 year to offer brief lifestyle counseling.

Pt-C constituted usual care, composed of an individual visit with an interventionist to receive advice and written materials on lifestyle modification for BP control consistent with JNC-7 guidelines.

Measurements
Measurements were obtained from all of the randomized physicians and all of the randomized patients at baseline and 6 and 18 months.

Physician Measurements
All of the physicians, regardless of treatment assignment, were asked to complete a self-administered questionnaire concerning demographics, education, training, characteristics of patients under their care, and usual practice patterns.

Patient Measurements
All of the study measurements were obtained during face-to-face clinic visits by trained, certified study personnel who were blinded to intervention assignment. For BP measurements, personnel were trained and certified using methods used in previous BP trials. Duplicate measurements were obtained with a calibrated automated appropriate-sized cuff after the participant had been seated quietly for ≥5 minutes. At each time point (baseline and 6 and 18 months), participants attended 2 study visits ~1 week apart. BP for that time point was defined as the mean of the 2 study visits (ie, 4 BP readings). For eligibility, hypertension was considered present on the basis of billing codes. For all other purposes, hypertension was defined as measured systolic (S)BP ≥140 mm Hg; diastolic (D)BP ≥90 mm Hg, or taking antihypertensive medication. BP treatment goals were defined on the basis of JNC-7 guidelines.

Height was measured once to the nearest 0.1 cm, using a calibrated, wall-mounted stadiometer. Weight was measured in duplicate with the participant wearing light, indoor clothes without shoes and using a high-quality, calibrated digital scale. Body mass index was calculated as the Quetelet Index (kilograms per meter squared). Dietary intake was assessed with the Block Food Frequency Questionnaire.

Physical activity was assessed by a calibrated, triaxial accelerometer (RT3, Stayhealthy, Inc) worn for ≥10 hours per day for ≥4 days over the course of a week, including 1 weekend day. Data are expressed as total weekly minutes of moderate-to-vigorous physical activity. Medications were self-reported and verified by study staff.

Dyslipidemia was defined as low-density lipoprotein cholesterol level ≥160 mg/dL or taking lipid-lowering medications. Diabetes mellitus was defined as fasting blood sugar >125 mg/dL or taking diabetes medication. The diagnosis of CKD was based on patient self-report. Although self-report of CKD is likely to be underestimated, self-report was used to identify patients with severe CKD, which would preclude eating the high-potassium DASH dietary pattern. For determining patient mix in MD-I feedback reports, these diagnoses were based on physician report.

Outcomes
The primary outcome was change in SBP from baseline to 6 months. Secondary outcomes included change in DBP at 6 months, BP change at 18 months, the effect of treatment on weight loss, dietary pattern, physical activity, fasting blood glucose and lipids, and the proportion of patients with adequate BP control.

Power and Statistical Analysis
The original study design defined the primary outcome as the proportion at goal BP, and, with a planned sample size of 500 patients, was powered to detect an effect size of 0.3. During the study it became clear that the proportion of patients who were at goal BP at baseline (assessed blinded to treatment group) was higher than anticipated on the basis of national statistics, potentially inducing a ceiling effect that could have left the study underpowered. Consequently, with the permission of the trial’s data and safety monitoring board, the primary outcome was changed to the continuous variable, change in SBP, with change in proportion at goal relegated to a secondary outcome. In addition, recruitment for the remaining study participants targeted those with BP above goal at baseline. The achieved sample size of 574 patients in 8 practices provided 80% power to detect a difference of 4 mm Hg.

Comparisons across treatment groups were adjusted for baseline value and cohort. There were no interim analyses. All of the participants were analyzed according to their original intervention assignment, but participants who did not complete the study measurements were not included in analyses. We compared baseline characteristics of completers and noncompleters using a χ² or t test (with Satterthwaite adjustment if indicated), and we performed a sensitivity analysis using last value carried forward. Intervention effects were consistent across cohort (assessed by a treatment-by-cohort interaction); accordingly, results are presented in aggregate.

Analysis of change in BP was performed using ANCOVA. The 2×2 factorial design allowed for tests of the main effect of MD-I, the main effect of Pt-I, and the interaction between the 2 interventions. For SBP and DBP, the “adjusted” (or “least-squares”) mean reflects the mean change in BP within each group after accounting for any differences in case mix between the groups. In addition, we considered the design to be equivalent to a 4-arm parallel trial and evaluated differences across pairs of intervention arms (MD-C/Pt-C, MD-I/Pt-C, MD-C/Pt-I, and MD-I/Pt-I). Similar analytic methods were applied to secondary outcomes. The effect of treatment group on the proportion “at goal” or “not at goal” was evaluated by χ² analysis.

Results
Eight primary care practices, composed of 32 physicians, were randomized to MD-I or MD-C (Figure 1). There were no significant differences between randomized groups with regard to physician age, sex, race, specialty, years in practice, or patient panels (Table 1). Approximately 31% reported that they were “quite familiar” with JNC-7 guidelines. All of the physicians in the MD-I group completed the 2 training modules. Quarterly feedback reports were based on physicians completing a mean of 36.4±16.4 forms per quarter on patients who were not HIP participants and 8.2±5.7 forms per quarter on patients who were HIP participants.

Within the 8 randomized practices, a total of 574 patients were randomized to Pt-I or Pt-C. Approximately 56% of screened patients were randomized (Figure 1), with most...
exclusions attributed to patients declining to participate. The mean age of patients was 60.5 years (range: 28.0 to 94.0 years), 61% were women, 37% were black, and 1% were Hispanic/Latino (Table 2). Most participants completed high school and reported that their income was “adequate” (93% and 85%, respectively), without differences across treatment groups. Body mass index ranged from 20.5 to 47.9 kg/m², but, on average, participants were obese (body mass index: ≥30 kg/m²). Three percent self-reported CKD. Billing code diagnosis of hypertension was confirmed in 97% of participants, who were taking a mean of 2 antihypertensive medications. Mean baseline BP was 133.1/74.1 mm Hg. At baseline, 60% of study participants were at goal BP.

Outcome data are presented for patients with both baseline and follow-up data for each variable. Follow-up data were available for 91.0% of randomized participants at 6 months and 88.5% at 18 months, without difference across treatment groups (Figure 1). At baseline, there were no significant differences between completers and noncompleters with regard to dietary intake, excretion of sodium, and weight. Completers were more physically active at baseline than noncompleters (36.5 versus 19.1 minutes per week; \( P = 0.02 \)), had higher baseline urinary potassium excretion (60.0 versus 53.1 mmol/24 hours; \( P = 0.05 \)), and had lower baseline SBP (132.7/73.9 versus 137.5/76.2 mm Hg; \( P = 0.05 \) for SBP, \( P = 0.17 \) for DBP).

With neither intervention (MD-C/Pt-C), SBP fell by a mean of 6.7/12.8 mm Hg at 6 months. With the physician intervention alone (MD-I/Pt-C), SBP fell by 5.3/12.1 mm Hg, and with the patient intervention alone (MD-C/Pt-I), SBP fell by 7.1/12.1 mm Hg (Figure 2A). With the combination of physician and patient interventions (MD-I/Pt-I), SBP fell by 9.7/12.7 mm Hg (\( P = 0.0072 \) compared with all other groups). In the main effects model, at 6 months there was no significant effect of MD-I (0.3 mm Hg; 95% CI: 1.5 to 2.2; \( P = 0.76 \)). In contrast, the main effect of Pt-I was a net reduction of 2.6 mm Hg (95% CI: −4.4 to −0.7; \( P = 0.01 \)). In addition, there was a significant interaction between MD-I and Pt-I (\( P = 0.03 \)), suggesting that the effect of Pt-I was enhanced by coincident exposure to MD-I. Similar results were seen for diastolic BP (Figure 2B). Figure 2 also demonstrates BP changes from baseline to 18 months. Although changes at 18 months were similar to changes at 6 months, they were no longer significant: at 18 months, the

### Table 1. Baseline Characteristics of Physicians

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall</th>
<th>Intervention</th>
<th>Control</th>
<th>( P^* )</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (total)</td>
<td>321</td>
<td>61</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>48 (10)</td>
<td>47 (13)</td>
<td>49 (7)</td>
<td>0.61</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>11 (34)</td>
<td>3 (19)</td>
<td>8 (50)</td>
<td>0.06</td>
</tr>
<tr>
<td>Black, n (%)</td>
<td>5 (16)</td>
<td>2 (12)</td>
<td>3 (19)</td>
<td>0.63</td>
</tr>
<tr>
<td>Family medicine (all others internal medicine), n (%)</td>
<td>17 (53)</td>
<td>8 (50)</td>
<td>9 (56)</td>
<td>0.72</td>
</tr>
<tr>
<td>Years postphysician degree, mean (SD), n</td>
<td>21 (10)</td>
<td>20 (12)</td>
<td>22 (8)</td>
<td>0.64</td>
</tr>
<tr>
<td>Clinic patients per day, mean (SD), n</td>
<td>21 (3)</td>
<td>22 (3)</td>
<td>20 (3)</td>
<td>0.13</td>
</tr>
<tr>
<td>Patients with hypertension per day, mean (SD), %</td>
<td>29 (16)</td>
<td>30 (14)</td>
<td>28 (18)</td>
<td>0.79</td>
</tr>
</tbody>
</table>

*Quite familiar* with JNC-7 guidelines, n (%) | 10 (31) | 5 (31)       | 5 (31)  | 0.99      |

*\( P \) is for intervention vs control.

### Table 2. Baseline Characteristics of Patients, Overall and by Treatment Group

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall</th>
<th>MD-C/Pt-C</th>
<th>MD-I/Pt-C</th>
<th>MD-C/Pt-I</th>
<th>MD-I/Pt-I</th>
<th>( P^* )</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (total)</td>
<td>574</td>
<td>141</td>
<td>148</td>
<td>140</td>
<td>145</td>
<td></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>60.5 (11.4)</td>
<td>60.7 (12.2)</td>
<td>61.6 (10.2)</td>
<td>59.0 (12.3)</td>
<td>60.7 (11.0)</td>
<td>0.27</td>
</tr>
<tr>
<td>Women</td>
<td>61</td>
<td>65</td>
<td>58</td>
<td>66</td>
<td>55</td>
<td>0.17</td>
</tr>
<tr>
<td>Black</td>
<td>37</td>
<td>42</td>
<td>31</td>
<td>44</td>
<td>33</td>
<td>0.07</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0.59</td>
</tr>
<tr>
<td>Current smoker</td>
<td>9</td>
<td>11</td>
<td>9</td>
<td>8</td>
<td>8</td>
<td>0.85</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>30</td>
<td>33</td>
<td>31</td>
<td>26</td>
<td>29</td>
<td>0.69</td>
</tr>
<tr>
<td>Body mass index, mean (SD), kg/m²</td>
<td>32.5 (5.5)</td>
<td>32.9 (5.7)</td>
<td>32.7 (5.4)</td>
<td>31.8 (5.5)</td>
<td>32.6 (5.2)</td>
<td>0.32</td>
</tr>
<tr>
<td>Hypertension</td>
<td>97</td>
<td>99</td>
<td>97</td>
<td>98</td>
<td>95</td>
<td>0.34</td>
</tr>
<tr>
<td>No. of BP medications, mean (SD)</td>
<td>2.0 (1.1)</td>
<td>2.1 (1.2)</td>
<td>2.0 (1.1)</td>
<td>2.0 (1.1)</td>
<td>1.9 (1.2)</td>
<td>0.58</td>
</tr>
<tr>
<td>SBP, mm Hg, mean (SD)</td>
<td>133.1 (16.1)</td>
<td>131.6 (14.6)</td>
<td>134.6 (15.7)</td>
<td>132.1 (17.6)</td>
<td>133.8 (16.3)</td>
<td>0.34</td>
</tr>
<tr>
<td>DBP, mm Hg, mean (SD)</td>
<td>74.1 (11.3)</td>
<td>73.3 (10.5)</td>
<td>74.3 (11.0)</td>
<td>73.3 (12.6)</td>
<td>75.3 (11.1)</td>
<td>0.39</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>48</td>
<td>49</td>
<td>54</td>
<td>44</td>
<td>44</td>
<td>0.28</td>
</tr>
<tr>
<td>Previous cardiovascular disease event</td>
<td>16</td>
<td>16</td>
<td>14</td>
<td>14</td>
<td>21</td>
<td>0.39</td>
</tr>
</tbody>
</table>

Data are percentage except where otherwise noted.

*\( P \) is for comparison across treatment groups.
main effect for the physician intervention was 0.3 ($P=0.81$), the main effect for the patient intervention was $-0.2$ ($P=0.89$), and the interaction was no longer significant. There were no statistically significant interactions for effects by race, sex, or age at either time point. Participants who were above goal BP at baseline had a 4.0 mm Hg greater reduction in SBP than patients in whom BP was already at goal at baseline ($P<0.0001$; 95% CI: 2.6 to 5.4). This finding suggests that the HIP interventions will be most effective in those who need it most, which may have implications for targeting implementation of this kind of intervention in clinical settings. These findings were confirmed in a separate nonparametric analysis, in a model that included physician as a covariate, and in a sensitivity analysis in which missing values were replaced by the last value carried forward.

Figure 3 shows the percentage of patients with BP at the JNC-7-defined goal. The proportion of patients with BP at goal increased in the first 6 months postrandomization, with significant differences across treatment groups ($P=0.03$), seemingly because of higher rates in those exposed to the patient intervention (MD-C/Pt-I and MD-I/Pt-I), but differences between treatment groups did not persist at 18 months.

Table 3 shows that, at baseline, treatment groups were comparable with regard to physical activity, dietary intake, and weight. In general, the effects on behavior of MD-I and Pt-I were independent of each other; the only significant interaction was for the effect on intake of F/V ($P$ for interaction=0.05). In the main effects analysis, there was no significant effect of either intervention on MV-PA. At 6 months, MD-I resulted in a significant increase in F/V intake and decreased total fat intake. Pt-I increased intake of F/V and dairy products and decreased intake of both total and saturated fat. Each of these dietary changes is consistent with the DASH dietary pattern. These changes were not reflected in the urinary excretion data (data not shown). Pt-I, but not MD-I, led to a significant reduction in weight ($-6.1$ and $+0.6$ lb, respectively; $P<0.0001$ for Pt-I main effect). At 18 months, the effect of MD-I on F/V intake was no longer significant, but the effect on total fat intake persisted. The effects of Pt-I on F/V, total fat, and saturated fat intake persisted, but effects on dairy intake and weight did not. There were no significant changes in the number of antihypertensive medications, but we did not measure changes in dose.

**Discussion**

The HIP trial demonstrated that, in the setting of primary care clinics, an intensive behavioral lifestyle intervention significantly reduced BP at 6 months, with evidence that this effect occurred because of adoption of a healthy dietary pattern and weight loss. A QI-type intervention for the primary care physicians treating these patients apparently did not lead to more effective BP management. However, a key finding of the trial was that the effect of the patient intervention was significantly enhanced by simultaneous exposure of the primary care provider to the QI-type intervention. MD-I may have enhanced the effect of Pt-I through several mechanisms. In previous research, providers reported a lack of confidence in addressing behavior change and patient lifestyle, and the training on lifestyle counseling included in the physician intervention may have increased their confidence and enhanced their counseling, reinforcing the lifestyle advice that patients were receiving in the patient intervention. Such reinforcement alone may not be sufficient to change patient behavior, but coupling it with intensive support for behavior change may have encouraged patients to adopt BP-lowering behaviors. In addition, the combined intervention may have changed the doctor-patient interaction in such a way that the physician was more likely to intensify antihypertensive treatment. Although there was no clear effect of the MD intervention on the number of antihypertensive medications prescribed, we were unable to assess changes in dose, which perhaps would more sensitively reflect intensification of therapy.
Our findings are consistent with a systematic review of QI interventions for BP control. In evaluating 44 articles, Walsh et al found that QI strategies that target the provider have limited effect compared with strategies that target the patient. The median reduction in BP associated with QI interventions that provided monitoring and feedback for providers was 1.5/0.6 mm Hg compared with 3.3/2.8 mm Hg for interventions that promoted patient self-management. In this systematic review, there was no opportunity to evaluate combinations of physician and patient strategies. However, subsequently, Roumie et al randomized 205 primary care providers to interventions that were similar but less intense than HIP: provider education plus an electronic alert system that added a single reminder for each patient, or provider education and alert plus patient education that added mailed, written advice concerning adherence to medication and lifestyle changes. This study was conducted largely in academic medical centers, in a study population that was older than HIP participants (mean age: 65 versus 60 years), 97% male (compared with 39% in HIP), and with higher baseline BP (157/82 versus 133/74 mm Hg). Despite these differences, results were similar: at 6 months, the group receiving provider education and alert plus patient education was 33% more likely to have SBP $< 140$ mm Hg than the group receiving provider education only ($P = 0.013$). Provider education plus alerts without patient education did not improve the SBP control rate.

Our provider intervention was unique in its emphasis on lifestyle counseling. There are numerous challenges to providing lifestyle counseling in the context of a primary care visit, including time, provider confidence in his or her own or the patient’s ability to change behavior, and lack of reimbursement for these activities. We expected that the physician training in the HIP provider intervention would increase lifestyle counseling, but the extent to which counseling...
occurred was based on physician self-report. It is possible that physicians in the intervention group were more likely to report counseling whether or not they were actually providing it, knowing that was expected of them. A discrepancy between reported and actual counseling may help explain the lack of effect of MD-I on BP.

Unlike the trial by Roumie et al., we tested the patient intervention alone. The HIP Pt-I is similar to what has been effective in previous studies but is unique in its application in this study in the community practice setting. In addition, the HIP Pt-I focused heavily on adoption of the DASH dietary pattern, which has been shown to lower BP and low-density lipoprotein cholesterol and has been associated with successful weight loss. In HIP, Pt-I significantly improved dietary pattern consistent with the DASH dietary pattern. The DASH dietary pattern is not specifically a low-salt diet, but the BP effect of DASH is increased by simultaneous reduction in sodium intake. Reducing sodium intake was a goal of the HIP Pt-I, but urinary excretion data did not suggest an effect. The lack of significant decrease in sodium excretion could reflect the limitations of a single 24-hour urine collection for assessing intake or an actual absence of change. Nonetheless, clinical trial and meta-analysis would suggest that the impact on BP of weight loss and DASH is greater than the impact of currently recommended sodium reduction. Thus, it may be advantageous that the HIP Pt-I had its predominant impact on DASH adherence and weight loss. In general, effects on BP were associated with changes in behavior. For example, patients who lost weight had a 2.1 mm Hg greater improvement in SBP compared with a reduction of 2.6/1.0 mm Hg in HIP (Pt-I main effect). This difference could well be within the variability of the effect estimate, or it could be because of increased effects in a younger population (mean age: 50 years in PREMIER versus 60 in HIP). However, PREMIER participants were otherwise similar to HIP participants (generally healthy, 36% men, 36% black, and BP 134/84 mm Hg at baseline). Therefore, the lesser effect on BP is more likely to reflect mild dilution of the intervention’s effect as the study design moves from academic medical centers (PREMIER) closer to an effectiveness trial conducted in community-based practices (HIP). Indeed the results of HIP may be more generalizable than other trials, because participants were recruited from community practices, received the intervention locally, and were diverse with respect to race, sex, and age.

As noted in the PREMIER Study and other trials, intervention effects on BP did not persist to the end of the study (18 months after randomization or 12 months after the intensive behavioral intervention for patients). We originally speculated that the 6-month outcomes would reflect the maximum impact of the patient intervention but might be too early to reflect maximum impact of the MD intervention. The 18-month outcomes presumably assess the durability of Pt-I, as well as the cumulative (perhaps maximal) effect of MD-I. We noted that there was some persistent effect on behavior (ie, improved dietary pattern and some weight loss), but there was no significant effect of either Pt-I or MD-I on BP at 18 months. The effect in the MD-I/Pt-I group at 18 months, however, was comparable to that found at 6 months.

The HIP study has 3 potential limitations. First, the analysis of primary outcome is based on those who completed follow-up. No imputation procedure was used for missing data, because no method was considered satisfactory, given that BP and other measurements were collected at baseline and then at the time of primary outcome assessment, with no intermediate measurements. Although a completers analysis is potentially subject to bias, the follow-up rate exceeded 91% at 6 months and 88% at 18 months, and a sensitivity analysis assuming no change in BP in noncompleters yielded similar results.

Second, because BP control rates were unexpectedly high at baseline, the primary outcome was changed from “proportion at goal BP” to “change in SBP.” However, the new primary outcome initially had been designated as an important secondary outcome, the decision to change the primary outcome was made blinded to treatment group effects and was reviewed and approved by the data and safety monitoring board, and the results are consistent.

Finally, the study population represents a relatively healthy cohort with high rates of BP control at baseline and limited comorbidity. In addition, only ~10% of potentially eligible patients were randomized. These factors suggest potential limitations to both the generalizability of the results and the implementation of the interventions.

**Perspectives**

The HIP behavioral intervention improved dietary pattern and lowered BP over 6 months, but the intervention was intensive, the effect size relatively small, and the effect did not persist. Implementation of a similar lifestyle intervention program would require further development to make it affordable, scalable within health systems, and able to produce sustained improvements in behavior and BP. The same is true for the HIP MD intervention. Improving the MD intervention might require integrated tools for easily assessing patient behavior and providing brief targeted advice within the context of the modern primary care practice. Nonetheless, given the potential impact of lifestyle modification on BP and the apparent role that doctors play in encouraging healthy behaviors, future development and testing of both patient and provider interventions should be a high priority.

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